

ANTIBIOTIC RESISTANT INFECTIONS

Mr. BURR Mr. President, I rise today to speak about legislation passed by the Senate yesterday, S. 3560. Antibiotic resistant infections are a serious and growing threat to public health in the United States, and I am pleased that S. 3560 contains a provision to address this threat.

The Institute of Medicine and the Infectious Disease Society of America, among others, have been warning us about antibiotic resistance for decades. We all know the therapeutics that work today against infections will be less effective over time as bacteria mutate into new resistant strains—and the pipeline of new antibiotics is nearly empty. My colleagues and I in Congress have been talking about the importance of developing new antibiotics for years, yet little has been done to create incentives to bring these anti-infectives to market.

In 2000, Senator KENNEDY stated on the Senate floor, “We are in a race against time to find new antibiotics before microbes become resistant to those already in use.” He could not have been more correct. That year, the Centers for Disease Control and Prevention estimated that methicillin-resistant *Staphylococcus aureus*, MRSA, was the cause of 126,000 hospitalizations in the United States. Today, that rate has tripled to nearly 400,000 hospitalizations per year and MRSA is the cause of an estimated 19,000 deaths every year.

The number of MRSA infections in hospitals has increased 10-fold since 1993. The University of North Carolina hospital systems reported earlier this year that 55 percent of patients with skin infections had a resistant strain.

Perhaps more frightening than hospital-acquired infections are those infections acquired in the community, including our elementary schools, athletic teams, and offices.

These numbers are more than statistics. Every Senator in Congress has constituents who have been impacted by MRSA. These super bugs are attacking and in several cases, killing healthy children and adults.

Earlier this year, six otherwise healthy high school football players at East Forsyth High School in Winston-Salem were diagnosed with MRSA. As the father of two boys who grew up in Winston-Salem and a former football player myself, this story hits close to home. Unfortunately, this outbreak was far from isolated.

According to the National Institute for Allergy and Infectious Diseases, antimicrobial resistance is driving up health care costs, contributing to the severity of disease, and increasing death rates from certain infections. In 2003, the economic burden for staph aureus associated hospital stays in the United States was \$14.5 billion.

As you may know, many pharmaceutical companies are abandoning or scaling back antibiotic research and

development in favor of more profitable drugs that treat chronic conditions. This is a regrettable, but understandable, development as market forces that would lead companies to consider investing in new antibiotic development are weak. Because antibiotics work so well and quickly in most cases, they are prescribed for only one or two weeks. That means antibiotics do not have as large a market as drugs that patients take for years. Bottom line—increasing the number of safe and effective antibiotics available in the United States is crucial to protecting the public health.

Section 4 of S. 3560, entitled “Incentives for the Development of and Access to Certain Antibiotics,” is an important step forward to help spur research on new antibiotics and provide incentives for the creation of additional generic antibiotics.

In the Food and Drug Administration Modernization Act of 1997, FDAMA, legislation I sponsored in the House, Congress moved antibiotics from section 507 to section 505 of the Food, Drug and Cosmetic Act because it did not make sense to have antibiotics separate from other drugs in the statute. Congress added language in FDAMA to ensure that antibiotics approved under section 507 would not be able to double dip on Hatch-Waxman benefits due to their new status under section 505. Those benefits include 3-year and 5-year data exclusivity and patent term extension for drugs. The FDAMA language said that any application for an antibiotic that was submitted to the Secretary could not “double dip.” As a result, companies have no access to Hatch-Waxman incentives to develop drugs based on active ingredients of the old 507 antibiotics submitted to, but not approved by, the Food and Drug Administration, FDA.

Equally important, the FDAMA language also negatively impacted generic drug companies’ ability to gain approval of and market generic equivalents of antibiotics approved under section 507.

Section 4 of S. 3560 says that any antibiotic that was the subject of an application submitted to the FDA, but not approved before FDAMA, can get the 3 year and/or 5 year Hatch-Waxman exclusivity or a patent term extension. According to the FDA, approximately 10 antibiotics fit this category of submitted but not approved and about half of those could never be approved because of issues with the active ingredients. According to a Congressional Research Service legal expert, the Patent Act would apply to this language, and it would be legally confusing if it did not mention the available Hatch-Waxman patent term extensions. For that reason, the provision authors added language providing the option of data exclusivity or a patent term extension.

This provision also addresses the negative consequences of the FDAMA language on generic drugs. Section 4 of S. 3560 includes language clarifying the

ability of generic drug companies to gain approval of and market generic equivalents of antibiotics approved under section 507.

This provision was included in Senate-passed S. 1082, the Food and Drug Administration Revitalization Act, and was agreed upon in Senate-House conference negotiations. Due to a lack of funding in H.R. 3580, the Food and Drug Administration Amendments Act, the House pulled this provision before passage of H.R. 3580, Public Law 110–85.

I commend Senators BAUCUS, GRASSLEY, KENNEDY, ENZI, and BROWN for making antibiotic incentives a priority at this time. It is important to encourage more treatments for the increasing number of resistant microbes we face.

IMPROVING ACCESS TO MAIN- STREAM FINANCIAL INSTITU- TIONAL ACT

Mr. AKAKA. Mr. President, too many Americans are left out of our mainstream financial institutions. Millions of working families do not have a bank or credit union account. The unbanked rely on alternative financial service providers to obtain cash from checks, pay bills, and send remittances. Many of the unbanked are low-and moderate-income families that can ill afford having their earnings diminished by reliance on these high-cost and often predatory financial services. In addition, the unbanked are unable to save securely to prepare for the loss of a job, a family illness, a down payment on a first home, or education expenses. There are few affordable alternatives for consumers who need small loans quickly.

We need to enact S. 3410, the Improving Access to Mainstream Financial Institutions Act of 2008. This legislation authorizes grants intended to help low- and moderate-income unbanked individuals establish credit union or bank accounts. The legislation also authorizes a grant program to encourage the development of affordable small loans at banks and credit unions.

Mr. President, I ask unanimous consent to have a letter of support from the Credit Union National Association, CUNA, for S. 3410 printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

AUGUST 1, 2008.

Hon. DANIEL AKAKA,
U.S. Senate,
Washington, DC.

DEAR SENATOR AKAKA: On behalf of the Credit Union National Association (CUNA), I am writing in regards to S. 3410, the “Improving Access to Mainstream Financial Institutions Act of 2008.” CUNA is the nation’s largest credit union advocacy organization, representing nearly 90 percent of our nation’s 8,300 state and federally chartered credit unions, their state credit union leagues, and their more than 90 million credit union members.

CUNA applauds your efforts to encourage low and moderate-income individuals to establish account relationships with mainstream financial institutions and to assist financial institution in offering low cost alternatives to payday loans.

Promoting thrift is one of the core missions of credit unions. Credit unions throughout the nation are dedicated to developing and offering products that provide consumers affordable payday lending alternatives. Credit unions also strive to improve their members' economic well-being through financial literacy programs and other initiatives. Because the intent of S. 3410 and the mission of credit unions are so well aligned, CUNA looks forward to the opportunity to work with you and your staff to suggest operational improvements to the bill as it makes its way through the legislative process.

On behalf of CUNA, our state leagues, member credit unions and their credit union members, I appreciate the opportunity to share our views on S. 3410, and we look forward to continuing to work with you on these and other issues important to consumers.

Sincerely,

DANIEL A. MICA,
President & CEO.

TRIBUTE TO JAMES K. "KENNY" PERRY AND JOHN B. "J.B." HOLMES

Mr. BUNNING. Mr. President, today I pay tribute to Kenny Perry and J.B. Holmes for their contribution to the success of the 2008 United States Ryder Cup team.

The 2008 Ryder Cup was recently held in my home State at the Valhalla Golf Club in Louisville, KY. On Sunday, the American team defeated the Europeans 16½ to 11½. This was their first Ryder Cup victory since 1999. If not for the remarkable performances by Mr. Perry and Mr. Holmes, this success would not have been possible.

Mr. Perry was born in Elizabethtown, KY, but calls Franklin, KY, his home. He started playing golf at the age of 7 and spent years perfecting his game. He later went on to attend Western Kentucky University and started golfing professionally in 1982. He has shown his dedication to the game of golf by building a public golf course in his hometown specifically designed for handicapped individuals. Perry's performance at this year's Ryder Cup was exceptional as he finished with a total record of two wins, one loss, and one tie. His achievements on and off the course are to be commended.

Mr. Holmes was born and currently resides in Campbellsville, KY. He has played golf most of his life, including playing for his local high school golf team as a third grade elementary student. He later went on to attend the University of Kentucky and started playing professional golf in 2005. His hard work and dedication have earned him the right to be named among the highest skilled golfers in the world. Mr. Holmes' performance at the 2008 Ryder Cup was one of the best. He finished with a total score of two wins, no losses, and one tie. It was a pleasure to

watch Mr. Holmes compete and I congratulate him on an outstanding performance.

I now ask my fellow colleagues to join me in congratulating Mr. Perry and Mr. Holmes for their remarkable performance and achievement. These two men have represented Kentucky and the United States well.

NATIONAL FIRST RESPONDER APPRECIATION DAY

Mr. CRAPO. Mr. President, I rise today to recognize and honor Idaho's first responders.

I have been joined by a bipartisan group of my Senate colleagues in passing a resolution that designates today, September 25, 2008, as National First Responder Appreciation Day. I would like to celebrate this day by showing my appreciation for the brave men and women who have risked life and limb and sacrificed family time and personal comfort to perform a task that is critical to citizens of the State of Idaho.

I would like to recognize the heroic efforts of all of Idaho's first responders, our firefighters, EMTs, medical personnel, and law enforcement officers. Thousands of first responders have made the ultimate sacrifice and have proven critical in leading the Nation through national tragedies like September 11 and natural disasters such as Hurricanes Ike and Gustav, through flooding in the Midwest, Hurricane Katrina and wildfires across the Western United States.

In Idaho, fire is a way of life. During the 2007 fire season, over 2 million acres burned, more than at any other time in Idaho's recorded history. Generally, Idaho's fire season begins in mid-July and extends into September, but in 2007, the Cascade Complex fire burned until the snow fell. The Cascade Complex fire was only one of several very large fires last year. The East Zone Complex fire in central Idaho burned over 300,000 acres, and the Murphy Complex fire in south-central Idaho burned over 600,000 acres. During this trying time, our first responders and firefighters went above and beyond the call of duty. Incident management teams and area command teams worked for weeks on end, battling flames and working to protect homes and lives. I have had the opportunity to visit fire camps and speak to these heroes who, like our veterans, often endanger their own lives to save the lives of others. Staff at the National Inter-agency Fire Center in Boise, ID, is to be commended for their tireless response coordination efforts.

While the severity of this fire season has not risen to the level of last year's fire season in Idaho, firefighters and other first responders have remained vigilant. The Oregon Trail fire in Boise, ID, began on August 25, 2008, when a brush fire, fed by 50 mph. winds, dry sage brush, high heat, and aided by sloped terrain, spread to the nearby Oregon Trail and Columbia Village sub-

divisions. The fire caused the destruction of ten homes, damage to nine others, and claimed the life of Mary Ellen Ryder, a professor at Boise State University. During this trying time, my thoughts and prayers go out to the Ryder family and others who have homes that have been lost or damaged. Thankfully, preplanning and preparation enabled Boise firefighters to avert the possibility of greater damage and loss. Firefighters arrived at Sweetwater Drive within 2 minutes of the first call, and they proceeded to risk their lives to draw a fire line between the burning houses and the other nearby subdivisions, protecting more than 1,000 homes and countless families.

The example of professionalism, strength, and bravery displayed by the Boise Police and Fire Departments during the events of the Oregon Trail fire is just one of many examples I could cite to illustrate the invaluable service wildland, municipal, and volunteer firefighters provide to our communities. Likewise, our EMTs, medical personnel, law enforcement, and others put their lives on the line daily to help others. Today, these efforts will receive recognition before the United States Senate and the American people.

IDAHOANS SPEAK OUT ON HIGH ENERGY PRICES

Mr. CRAPO. Mr. President, in mid-June, I asked Idahoans to share with me how high energy prices are affecting their lives, and they responded by the hundreds. The stories, numbering well over 1,000, are heartbreaking and touching. To respect their efforts, I am submitting every e-mail sent to me through an address set up specifically for this purpose to the CONGRESSIONAL RECORD. This is not an issue that will be easily resolved, but it is one that deserves immediate and serious attention, and Idahoans deserve to be heard. Their stories not only detail their struggles to meet everyday expenses, but also have suggestions and recommendations as to what Congress can do now to tackle this problem and find solutions that last beyond today. I ask unanimous consent to have today's letters printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

If you want to really understand what is going on with our energy crises, please view all eight sections of: <http://video.google.com/videoplay?docid=3870461488930715065>.

BRAD AND DEE.

These rising fuel prices are hurting my family and our business! We own a logging company which, being all mechanized, requires use of a lot of fuel. In addition, our jobs are usually 100 miles or more away and even with our employees commuting together, the cost is outrageous. In the logging industry, it is not all that easy to pass the cost on to the customer. The jobs we are doing right now were bid on last year; therefore the price is set and was set without the prediction that the fuel prices were going to be this high. Our employees can forget